HOUSE . . . . . No. 2097

By Ms. Fox of Boston, petition of Gloria L. Fox and others for legislation to establish a high containment biological research laboratory health and safety program by the Department of Public Health. Public Health.

The Commonwealth of Massachusetts

PETITION OF:

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In the Year Two Thousand and Seven.

AN ACT PROMOTING RESEARCH AND PROTECTING PUBLIC SAFETY AND ENVIRONMENT.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 17 of the General Laws, as appearing in the 2004 official edition is hereby amended by inserting after Section 17 the following:- Section 18. Biological Agents Registry Program (a) Definitions. As used in this section the following words shall have the following meanings:—

"Biological agent," any microorganism (including bacteria, virus, fungus, and protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing: death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water,

equipment, supplies, or material of any kind; or deleterious alteration of the environment.

"Department," the Department of Public Health.

"Person," any state, public, or private corporation or authority, any individual, trust, firm, joint stock company, partnership, association, or other entity, or any group thereof, and any officer, employee, or agent of such person, any group of persons, and any agency or political subdivision of the Commonwealth or of the federal government.

"Program," the Biological Agents Registry Program.

"Select Agents and Toxins" a biological agent or toxin as defined in Title 42, Part 73 of the Code of Federal Regulations, Title 9, Part 121 of the Code of Federal Regulations, or Title 7, Part 331 of the Code of Federal Regulations.

"Toxin," any toxic material or product of plants, animals, microorganisms (including bacteria, virus, fungus, rickettsiae, or protozoa), or infectious substance, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes: any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

(b) There is established in the department a Biological Agents Registry Program.

(c) The Biological Agents Registry shall:—

(1) Identify the select agents and toxins, and other biological agents and toxins, as determined by the department, possessed and maintained by any person in the Commonwealth; and

(2) Contain other information as required by regulations of the department.

(d) The department shall adopt regulations for the implementation of the program that:—

(1) Determine and list the biological agents and toxins required to be reported under this section, which shall include:—

i. All select agents and toxins, provided that the department may exempt select agents and toxins that Title 42, Part 72 or 73 of the Code of Federal Regulations, Title 9, Part 121 of the Code of Federal Regulation, or Title 7, Part 331 of the Code of Federal Regulations exempt from their provisions; and

ii. Other biological agents and toxins as determined by the department.

(2) Designate the persons required to make reports and the specific information required to be reported;

(3) Designate time limits for reporting, the form of reports, and the persons to whom reports are to be submitted;

(4) Require local boards of health to be informed of the location and nature of the biological agents and toxins in the registry that are located within the local jurisdiction;

(5) Provide for the release of information in the Biological Agents Registry to:—

i. Municipal, state and federal law enforcement agencies and the Centers for Disease Control and Prevention pursuant to a communicable disease or laboratory-acquired infection investigation commenced or conducted by the department or municipal, state, or federal law enforcement agency having investigatory authority, or in connection with any investigation involving a release, spread, theft, illicit sale, or loss of biological agents;

ii. The Massachusetts emergency management agency and the Massachusetts department of the environmental protection for the purposes of planning for the protection of the public in relation to the release of a biological agent and the prevention of a release of a biological agent; and

iii. The Massachusetts emergency medical services system for the purposes of providing certain specified information to:-

(A) A police officer or firefighter responding to an emergency; and

(B) An emergency medical services provider performing emergency services responding to a fire or other emergency, or dispatched on a call for emergency services;

(6) Establish a process for persons that possess and maintain select agents and toxins and other biological agents and toxins to alert appropriate authorities of unauthorized possession or attempted possession of such biological agents or toxins

(e) A person that possesses and maintains biological agents and toxins shall report to the department the information required by the department for inclusion in the Biological Agents Registry unless the department determines that the select agents and toxins, certified laboratory, or facility is exempt from the requirements for the inter-

state shipment of etiologic agents under Title 42, Part 72.6(h) or Part 72, Appendix A of the Code of Federal Regulations.

(f) Information prepared for or maintained in the Biological Agents Registry shall be subject to Chapter 66 of the General Laws, provided that information released from the Registry is not consequently a public record and a person to whom information has been released from the Registry may not release the information unless such release is approved by the department.

(g) A person who violates a provision of this section is guilty of a misdemeanor and on conviction is subject to a fine not exceeding $1000 for the first offense and not exceeding $5000 for each subsequent conviction for a violation of the same provision. Each day a violation is continued after the first conviction is a subsequent offense.

Section 19. High Containment Biological Research Laboratory Health and Safety Program.

(a) Definitions. As used in this section the following words shall have the following meanings:—

"Biological agent," any microorganism (including bacteria, virus, fungus, and protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing: death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

"Biosafety in Microbiological and Biomedical Laboratories" or "BMBL," a publication that lists the standards and special microbiological practices, safety equipment and facilities constituting Biosafety Levels 1-4, most recent edition, published by the United States Department of Health and Human Services, Public Health Service, the Centers for Disease Control and Prevention and the National Institutes of Health. If the publication is discontinued, the most recent edition shall remain in effect as thereafter modified from time to time by regulation of the department.

"Biosafety Level 3 laboratory" or "BSL3 laboratory," a laboratory that is designed, equipped, or operated as a Biosafety level 3 laboratory as defined by the United States National Institutes of Health

Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

"Biosafety Level 4 laboratory" or "BSL4 laboratory," a laboratory that is designed, equipped, or operated as a biosafety level 4 laboratory as defined by the United States National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). "Department," the Department of Public Health.

"Facility," a building or combination of buildings under common control and ownership containing one or more laboratories subject to a common Institutional Biosafety Committee.

"High Containment Biological Research Laboratory," a BSL3 or BSL4 laboratory.

"Laboratory," a room or rooms that are used primarily for biological research, development, non-routine testing, or experimentation activity, or any room or rooms where vertebrate animals are contained under animal biosafety levels three and four as described in NIH Guidelines/BMBL Section IV. The word "laboratory" shall also include those rooms that directly serve a laboratory and are within the containment area.

"National Institutes of Health Guidelines" or "NIH Guidelines," the National Institutes of Health Guidelines for Research Involving Recombinant Molecules, as amended from time to time. If the National Institutes of Health shall discontinue or abolish said guidelines, the most recent guidelines shall remain in effect as thereafter modified from time to time by regulation by the department.

"Person," any state, public, or private corporation or authority, any individual, trust, firm, joint stock company, partnership, association, or other entity, or any group thereof, and any officer, employee, or agent of such person, any group of persons, and any agency or political subdivision of the Commonwealth or of the federal government.

"Program," the High Containment Biological Research Laboratory Health and Safety Program.

"Select Agents and Toxins," a biological agent or toxin as defined in Title 42, Part 73 of the Code of Federal Regulations, Title 9, Part 121 of the Code of Federal Regulations, or Title 7, Part 331 of the Code of Federal Regulations.

"Toxin," any toxic material or product of plants, animals, microorganisms (including bacteria, virus, fungus, rickettsiae, or

protozoa), or infectious substance, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes: any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

(b) There is established in the department a High Containment Biological Research Laboratory Health and Safety Program.

(c) The program shall provide standards for the location, operation, and maintenance of high containment biological research laboratories and the oversight of such laboratories to protect the safety of laboratory workers, the public, and the environment from select agents and toxins.

(d) The department shall adopt regulations for the implementation of the program that:—

(1) Set criteria for determining appropriate locations for siting a building with a BSL4 laboratory, including whether a BSL4 laboratory may be created within an existing building, that at a minimum include that:—

i. Sites shall not be within a floodplain, near a property whose regular use could significantly endanger the site through fire or explosion, or near an area of high traffic congestion that might impede emergency access or evacuation or endanger motorists;

ii. Sites shall have sufficient land available to provide for a reasonable buffer around the building, a minimum of 150 unobstructed feet in every direction;

iii. Other criteria for consideration include: the proximity of flood plains, wetlands, waterways, and water bodies; the relationship of the site to groundwater elevations; the nature and extent of residential areas and schools through grade twelve in proximity to the site; the availability and suitability of access roads to the site, including the ability of first responders to access the site in an emergency; the potential for adverse public health and safety impacts; the potential impact of increased traffic volume on roads to the site; and the potential threat of a terrorist attack on or infiltration of the building.

(2) Provide a process to determine whether to approve the siting of a new BSL4 laboratory that includes:—

i. An application to be completed by a person wishing to site a building with a BSL4 laboratory or add a BSL4 laboratory to an existing building that did not have a BSL4 laboratory;

ii. The department holding a public hearing on the application in the municipality where the laboratory would be located;

iii. The department, the department of environmental protection, the board of health of the municipality in which the facility would be located reviewing the application and approving the siting if they determine that the proposed site and building would not constitute a threat to the public health or safety or the environment;

iv. The decision on the siting is made in writing with findings as to why the decision was made;

v. The approval or denial of siting may be appealed pursuant to provisions of Section fourteen of Chapter thirty A;

(3) Require each facility with a BSL4 laboratory that has been approved as required by subsection (2) to submit to the department the construction plans for the facility, construction schedule, the application submitted to the National Institutes of Health (NIH), if applicable, the as-built plans when completed, and documentation of third-party commissioning of the facility.

(4) Assure that high containment biological research laboratories meet or exceed federal guidelines for health and safety practices, including that:—

i. Each facility with a high containment biological research laboratory complies with the most current versions of the following guidelines:—

NIH Guidelines; BMBL; and Guidelines on Primary Containment for Biohazards (Centers for Disease Control/NIH); or more protective regulations that the department might adopt.

ii. Each facility with a high containment biological research laboratory shall establish an Institutional Biosafety Committee (IBC) in accordance with the NIH Guidelines, whether it is NIH funded or not. At least two members of the IBC shall be residents of the municipality in which the facility is located and shall be independent of the facility, its contractors, and consultants. One such member shall be appointed by the department and the other shall be appointed by the local board of health. A member appointed by the department or local board of health may be rejected by the facility only for good cause.

iii. An IBC shall comply with NIH Guidelines applicable to IBCs for all research in high containment biological research laboratories, whether recombinant DNA research or not, and may be further regulated by the department. Each IBC for a facility with high containment biological research laboratory shall, at a minimum:—

(A) Provide the department with a complete list of all members of the IBC, including member's name, title, business mailing address, phone number, fax number, e-mail, and curriculum vitae. The list and curriculum vitae shall be updated with any changes at least annually.

(B) Review and approve all projects in facilities operating a high containment biological research laboratory prior to the projects commencing. A protocol registration document, as defined by the NIH guidelines, shall be required for all approved IBC projects with select agents and toxins and other regulated agents requiring BSL3 or BSL4 containment. The documents shall be sent to the department and are subject to Chapter 66 of the General Laws.

(C) Take and keep minutes of IBC meetings that conform to the NIH Guidelines and provide the minutes to the department. The minutes shall be accessible for members who do not attend the meetings. The minutes shall include, but not be limited to: IBC members present at the meeting; a description of any current or pending research; any comments or concerns made at the meeting; and any voting, administrative matters, accident reporting or compliance issues discussed. The department may provide the minutes to the local board of health upon request.

(D) Inspect the high containment biological research laboratories at least annually and submit the results of the inspections to the department.

(E) Meet at least annually with a representative of the department to review safety procedures, discuss health issues relating to operation of its facility, and such other issues identified by the department.

(F) Hold at least one public meeting annually to a report on health and safety issues at the facility and take public comments about the facility.

(5) Require prior approval by the department for research that may or is intended to:—

i. Enhance the harmful consequences of a biological agent or toxin. Harmful consequences include the ability to critically alter

normal biological functions, or inflict damage on public health resources, materiel, and public safety. Enhancement includes augmenting properties such as virulence, infectivity, stability, transmissibility, or the ability of the biological agent or toxin to be disseminated;

ii. Disrupt immunity or the effectiveness of an immunization;

iii. Confer to a pathogenic agent or toxin resistance to clinically or agriculturally useful prophylaxes or therapeutics against that agent or toxin;

iv. Facilitate the ability of a biological agent or toxin to evade detection methodologies;

v. Increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin;

vi. Alter the host range or tropism of a pathogenic agent or toxin;

vii. Enhance the susceptibility of a host population, including by immuno-modulation of the host to increase pathogenicity; or

viii. Generate a novel pathogenic agent or toxin or reconstitute an eradicated or extinct pathogenic agent. A novel agent is an agent that has not existed previously and is considered unique based on biological or other properties and traits. Such approval may be granted only upon a showing that the facility has taken special precautions to minimize or eliminate health and safety risks arising from such research.

(6) Require each facility with a high containment biological research laboratory to complete a permit application and obtain a permit from the department to operate its high containment biological research laboratories. Said permits shall contain the terms and conditions the department determines are necessary to protect worker and public health and safety and the environment. Said permits shall not exceed five years in duration but may be renewed or reissued by the department after receipt of a new completed permit application that meets regulatory requirements. The department may issue or renew a permit only upon finding that no condition or circumstance exists in the facility that is prejudicial to worker or public health and safety or the environment. The department may suspend or revoke a permit upon finding that a condition or circumstance exists in the facility that is prejudicial to worker or public health and safety or the environment.

(7) Require each facility with a high containment biological research laboratory to have a medical surveillance plan created in consultation with a licensed physician experienced in occupational health or infection control and familiar with biological laboratory exposures and informed about select agents and toxins. The purpose of the plan is to establish employee and researcher occupational health records, document and require inoculation for diseases when a safe vaccine is available, screen for illness among laboratory workers, require reporting of laboratory accidents, monitor and track releases and laboratory-acquired infections and spreads, and report within the facility and to appropriate government entities. The specifics of the medical surveillance and infection control protocol must meet standards established by the department and be approved by the department. The medical surveillance plan shall be implemented through an employee experienced in occupational health or infection control, familiar with biological laboratory exposures, and informed about select agents and toxins. The employee shall also:—

i. Report any accidental or intentional human exposure to a pathogenic biological agent or toxin, or reasonable likelihood of such exposure, to the department as soon as possible and in no case more than 24 hours after learning of the exposure;

ii. Report any accidental or intentional release or spread of a pathogenic biological agent or toxin, or reasonable likelihood of a release or spread, outside the containment area of a BSL 3 or BSL4 laboratory to the department as soon as possible, and in no case more than 24 hours after the release. The report also shall be provided to the board of health in the municipality in which the facility is located and any other municipality affected by the release.

iii. Provide the IBC with a report of all incidents, accidents, and other events that caused or are suspected to have caused a threat to the public health, death, illness, or bodily injury to any person in the laboratory, as they occur, but no later than 3 days after the incident.

(8) Require each facility with a high containment biological research laboratory to have and implement a plan to provide adequate training for the proper handling of pathogenic biological agents and toxins that might be present in the laboratory. Such training shall include, but not be limited to, decontamination methods, personnel safety precautions and work habits, early warning disease surveillance, and accident response actions and

notifications. The facility shall provide a training plan to its IBC and the department for approval and shall update the plan annually, if necessary. The training plan shall ensure that all laboratory staff and researchers, including the principal investigator for each facility, are trained adequately and that the principal investigator participates in the creation and implementation of the training plan. No individual other than a local, state or federal government representative requiring access for regulatory compliance or investigative purposes may enter a high containment biological research laboratory located within a facility without first completing the facility's training plan.

(9) Require each facility with a high containment biological research laboratory to have and implement a waste management and decontamination plan approved by the department.

(e) A facility with a high containment biological research laboratory shall develop an emergency response plan, in conjunction with local and state officials, that addresses security threats and releases and spread of pathogenic biological agents and toxins. The emergency response plan shall comply with local, state or federal plans already in existence. The plan must address such events as severe weather (such as hurricanes and floods), earthquakes, power outages, terrorism, and other natural, accidental, or intended disasters or emergencies. The emergency response plan shall at a minimum address the following:—

(1) The hazards associated with the use of the select agents and toxins and special procedures needed to address the hazards of specific select agents and toxins.

(2) Personnel roles, lines of authority, training, and communication.

(3) Emergency assessment and prevention.

(4) Site security and control.

(5) Evacuation routes and procedures.

(6) Decontamination.

(7) Emergency medical treatment and first aid.

(8) Emergency alerting and response procedures.

(9) Personal protective and emergency equipment.

(10) Regularly scheduled preparedness exercises in coordination with local public health and safety officials.

(11) Critique of response and follow-up after an incident has occurred.

(12) Communication to the public and news media.

(f) A facility with a BSL4 laboratory shall coordinate with a hospital within a five mile radius of the facility for a medical response to human exposure to a pathogenic biological agent or toxin, and do so in conformity with existing public health guidelines and regulations. If there is no hospital medically equipped to coordinate this type of response within a five mile radius of said facility, then the coordination shall be performed at the closest hospital to the facility so equipped. Said coordination shall include, but not be limited to, addressing transportation, isolation, and quarantine issues as appropriate to the diseases caused by select agents and toxins at the facility. If the closest hospital has created a plan in collaboration with the department under the Bioterrorism Grant Program, the facility is not required to pay for the cost of annual drills.

(g) Every facility that has a high containment biological laboratory shall purchase property and general liability insurance. The insurance shall provide compensation for harm that would be caused to facility workers and the public in the event of a release of a toxin or agent or other hazardous exposure to dangerous pathogens, and from damages caused by a terrorist attack on the facility.

(h) No employee, researcher, or student shall be required to conduct scientific research, experimentation, or study or take other action in a facility with a high containment biological research laboratory that violates any provision of this section or has reasonable potential to adversely affect public or worker health, safety, or the environment.

(i) A facility with a high containment biological research laboratory shall not take any retaliatory action against an employee, researcher, or student in the facility because that person discloses or threatens to disclose to a supervisor or a public body an activity, policy or practice that the employee, researcher or student reasonably believes is in violation of this section or objects to or refuses to participate in any activity, policy or practice that the employee, researcher or student reasonably believes is in violation of this section.

(1) The protection against retaliatory action shall not apply to the public disclosure of confidential or proprietary information, trade secrets or other confidential materials unless the employee, researcher or student makes such disclosure directly and exclusively

to the office of the attorney general or the department. The department shall not publicly disclose any such confidential information, but shall submit the information to the Attorney General forthwith. (2) An employee, researcher or student aggrieved by a violation of this subsection may, within two years, file a complaint with the attorney general, who may bring an action in the name of the Commonwealth against the facility alleged to have violated this section. Provided further, that within ninety days of receiving said complaint, the attorney general shall notify the complainant in writing as to whether he intends to bring an action in the name of the Commonwealth. If the attorney general declines to bring an action based on the complaint filed, the aggrieved employee, researcher or student may, within one year, institute a civil action in the superior court. Any party to said action shall be entitled to claim a jury trial. All remedies available in common law tort actions shall be available to prevailing plaintiffs. These remedies are in addition to any legal or equitable relief provided herein. The court may:—

(i) issue temporary restraining orders or preliminary or permanent injunctions to restrain continued violation of this section;

(ii) reinstate the employee, researcher or student to the same position held before the retaliatory action, or to an equivalent position;

(iii) reinstate full fringe benefits and seniority rights to the employee, researcher or student;

(iv) compensate the employee, researcher or student for three times the lost wages, benefits and other remuneration, and interest thereon; and

(v) order payment by the facility of reasonable costs, and attorneys' fees.

(3) In any action brought by an employee, researcher or student under subsection (2), if the court finds said action was without basis in law or in fact, the court may award reasonable attorneys' fees and court costs to the facility. An employee, researcher or student shall not be assessed attorneys' fees if, after exercising reasonable and diligent efforts after filing a suit, the employee, researcher or student moves to dismiss the action against the facility, or files a notice agreeing to a voluntary dismissal, within a reasonable time after determining that the facility would not be found liable for damages.

(4) Nothing in this subsection shall be deemed to diminish the rights, privileges or remedies of any employee, researcher or student

under any other federal or state law or regulation, or under any collective bargaining agreement or employment contract.

(5) A facility with a high containment biological research laboratory shall publicly display notices designed to inform its employees, researchers and students of their protections and obligations under this subsection, and use other appropriate means to keep its employees, researchers or students so informed. Each notice posted pursuant to this subsection shall include the name of the person or persons the facility has designated to receive written notification of a suspected violation of this section.

(j) A facility with a high containment biological research laboratory shall have a security plan developed in coordination with state and local public safety officials. The security plan shall describe the deployment of security guards; the number of guards at each facility; other protective measures, including, coordination of security response with Federal, State, and Local authorities; restricted personnel access to each BSL3 and BSL4 laboratory; perimeter site security, internal site security, and fire protection barriers; and background security clearance for employees and prospective employees. If, at any time, the department of public safety determines that the security plan or implementation of the security plan for a BSL3 or BSL4 facility or laboratory is insufficient to ensure its security, the municipality or department of public safety shall submit to the facility a report that identifies the vulnerability of the facility or laboratory, and recommended actions to eliminate the vulnerability. Said recommendations or other remedial actions shall be implemented by the facility immediately.

(k) To ensure compliance with this section and to protect the public health and safety and the environment, the department shall have the authority to review all documentation relating to the operations of a high containment biological research laboratory and conduct physical inspections of any such laboratory, and any other part of a facility that supports the laboratory, with or without prior notice; so long as such inspections are conducted at reasonable times and in a manner that maintains the health and safety systems of the laboratory.

(l) A person who willfully or knowingly violates this section or a regulation promulgated pursuant to this section is subject to judicially imposed criminal and civil penalties as well as civil

administrative penalties. Each day that a violation occurs or continues constitutes a separate violation. A violation may be punished by the administrative imposition of a penalty of not less than $100 and not more than $25,000 for each day of violation. A violation may be punished by a fine not less then $100 and not more than $25,000, or by imprisonment for not more than two years in the house of correction. Punishment imposed under this section does not preclude any other penalty prescribed by law.

(m) If a facility or laboratory remains in violation of this section or a regulation promulgated pursuant to this section after written notice from the department without taking reasonable steps to alleviate the violation, the department shall have the authority to close the facility or laboratory until the violation is remedied. If the department finds that an imminent and substantial threat to worker or public health or safety or the environment exists in a facility or laboratory, it may request the attorney general bring suit or an action for injunctive relief.

(n) Each municipality in the Commonwealth shall have the authority to regulate and prohibit high containment biological research laboratories within its jurisdiction. If a municipality has a regulatory program for high containment biological research laboratories that the department finds is at least as protective of worker and public health and safety and environment as this program, upon request of the municipality the department may certify the municipal program to operate in the place of this program in the municipality.

SECTION 2. The Department of Public Health shall adopt regulations to implement this act within one year after the effective date of this act.

SECTION 3. Section 19(d)(2), concerning whether to approve the siting of a new BSL4 laboratory, shall not apply to any building intended to include a BSL4 laboratory that has a building permit and is under construction as of the effective date of this act.